TearLab™

OSMOLARITY SYSTEM - **USER MANUAL**

CLIA WAIVED

OSMOLARITY SYSTEM ⊕ CONTENTS

CLIA CONSIDERATIONS

The TearLab Osmolarity System is a CLIA-waived test system for human tears. Each laboratory or testing site using the TearLab Osmolarity System must have a CLIA Certificate of Waiver before starting testing. To obtain a Certificate of Waiver, call your state department of health or TearLab Customer Support at 1-858-455-6006 for an application (Form CMS-116). TearLab can provide the phone number of your state department of health and assist you in filling out the application. The TearLab Osmolarity System is a waived test so long as it is used according to the instructions in the Package Insert. Any modification by the laboratory to the test system or the test system instructions will result in this test no longer meeting the requirements for waived categorization. A modified test is considered to be high complexity and is subject to all applicable CLIA requirements.

INCLUDED CONTENTS:

TEARLAB READER

PEN

ELECTRONIC CHECK CARDS

- TearLab Reader
- (2) TearLab individually boxed Pens with magnetic cardboard sleeves, Instructions for Use, and a set of adhesive identification labels
- Set of (2) Electronic Check Cards with Instructions for Use
- TearLab User Manual
- TearLab Quick Reference Guides
- Power Supply
- Power Cord(s)

SOLD SEPARATELY:

OSMOLARITY TEST CARDS

OSMOLARITY CONTROL SOLUTIONS

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OSMOLARITY SYSTEM → PRODUCT OVERVIEW

The TearLab Osmolarity System is intended to measure the osmolarity of human tears to aid in the diagnosis of Dry Eye Disease in patients suspected of having Dry Eye Disease, in conjunction with other methods of clinical evaluation.

Tears fulfill an essential role in maintaining ocular surface integrity, protecting against microbial challenge, and preserving visual acuity. These functions, in turn, are critically dependent upon the composition and stability of the tear film structure.[1]

Osmolarity is a basic and essential aspect of physiologic homeostasis in body fluids. Small deviations in homeostasis, such as variations in pH, temperature, glucose and oxygen concentrations, and osmotic pressure, activate physiological mechanisms to return that variable to its set point. The body is able to regulate osmolarity of body fluids within very narrow limits through various mechanisms of osmoregulation, such as the compensation and correction of fluid volume and salt concentration. Hyperosmolarity of any body fluid, including tear fluid, indicates a disorder in the body's ability to regulate homeostasis and is a basic indication of a physiological disorder. The higher the osmolarity, the more concentrated the tear films.[2]

Hyperosmolarity has been described in the literature as a primary marker of tear film integrity.[3] When either the quantity or the quality of secreted tears is compromised (known as aqueous deficient or evaporative Dry Eye Disease), an increased evaporation rate leads to a concentrated tear film (increased osmolarity) that places stress on the corneal epithelium and conjunctiva.

The TearLab Osmolarity Test Card, in conjunction with the TearLab Osmolarity System, provides a quick and simple method for determining tear osmolarity using nanoliter (nL) volumes of tear fluid collected directly from the eyelid margin. To perform a test, attach a new Test Card onto the Pen and touch the tip of the Pen to the tear fluid meniscus, located above the lower eyelid. After a successful collection, dock the Pen into the Reader, which will display a quantitative tear osmolarity test result on the liquid crystal display (LCD). The TearLab Osmolarity System simplifies the tear-collection process by eliminating the need to transfer tear fluid samples and reducing the risk of evaporation.

PRINCIPLES OF THE PROCEDURE

The TearLab Osmolarity Test utilizes a temperature-corrected impedance measurement to provide an indirect assessment of osmolarity.[4] After application of a calibration curve to the steady-state electrical impedance of the tear fluid, osmolarity is calculated and displayed as a quantitative numerical value.

OSMOLARITY SYSTEM → SYSTEM COMPONENTS

TEARLAB OSMOLARITY SYSTEM READER

The Reader is a portable countertop unit that calculates and displays the osmolarity test result. The Reader has an LCD screen, a keypad, and an external AC power supply. Left and right cradles allow two Pens to dock into the Reader. When Pens are docked, the Reader automatically converts the tear fluid sample data into an osmolarity measurement and displays the reading on the LCD.

TEARLAB OSMOLARITY SYSTEM PEN

The Pen is designed to hold the Test Card and facilitate safe, simple tear fluid collection. The Pen electronics confirm the proper attachment of the Test Card onto the Pen, detect the presence of tear fluid in the Test Card, and signal when a tear fluid sample has been successfully collected. Powered by a permanent rechargeable battery, the Pen provides a mechanical/electrical interface to convey data to the Reader automatically when docked. Each TearLab Osmolarity System includes two Pens to allow sequential tear fluid sample collection from multiple patients or from the left and right eyes of a single patient.

TEARLAB OSMOLARITY TEST CARD

Each Test Card is a single-use, individually packaged, nonsterile, polycarbonate microchip containing (a) microfluidic channel to collect 50 nanoliters (nL) of tear fluid by passive capillary action, and (b) gold electrodes embedded in the polycarbonate microfluidic channel to enable on-board measurement of tear osmolarity. Test Cards are clinically hygienic and have a protective cover that should be removed only after the Test Card has been successfully attached onto the Pen and immediately prior to tear collection. Each Test Card is imprinted with a code that must be entered into the Reader at the time of testing. Designed to work in conjunction with the TearLab Pen, the Test Card does not contain chemicals or reagents, and collects tear fluid in less than one second. Please note that TearLab Osmolarity Test Cards are not included with the TearLab Osmolarity System and must be purchased separately.

TEARLAB ELECTRONIC CHECK CARDS

Two identical, blue, reusable Electronic Check Cards are provided as a procedural quality control to confirm the function and calibration of the TearLab Osmolarity System within manufacturer specifications. The Electronic Check Cards can be used simultaneously for quality control testing, one with each Pen. The Electronic Check Cards can be used to verify the function of the TearLab if it is mishandled or the Pens are dropped. Tear fluid samples cannot be collected with the Electronic Check Cards.

OSMOLARITY SYSTEM ⊕ INSTALLATION

A Reader, two Pens, a power supply, power cord(s), and Electronic Check Cards are delivered together with Osmolarity System User Manual(s) and Quick Reference Guide(s). Open the carton on a stable surface, remove the components, and set them on a flat surface with at least two inches of space around the Reader. The Reader and Pens should not be used in direct sunlight and should be at ambient temperature (15°–30°C/59°–86°F) before use. After the Reader is switched ON, a 25-minute warm-up before use is required. The Reader will indicate when it is ready for use.

1. Each Pen comes with a set of identification labels that can be affixed to the back of the Pen to distinguish one Pen from the other. Affix labels to the back of each Pen, if desired. Each Pen is also supplied with a reusable magnetic cardboard sleeve for long-term storage. DO NOT DISCARD. (See "Long-Term Pen Storage" section on page 3 of this manual.)

2. Insert each Pen into a cradle. The Reader has two cradles to allow simultaneous docking of both Pens. Either Pen will function in either cradle.

3. Select the power cord that corresponds to your local electrical outlet configuration. Connect the power cord to the power supply, plug the power cord into an electrical outlet, and connect the power supply to the back of the Reader. Locate the switch on the back of the Reader and set to the ON ⊙ position.

WARNING: *Modification of this equipment is not recommended. This may cause a safety hazard and will nullify the manufacturer's warranty. Do not locate the TearLab System directly in front of the power outlet. The power cord and plug must be accessible for removal from the power outlet.*

INITIAL SETUP AND MENU NAVIGATION

- Upon first use, press the MENU Key ☰ once to enter the Menu Mode and setup screen.
- Press the RECALL Key ⮌ below the UP and DOWN arrows to scroll.
- Press the OK Key OK to choose a menu item.
- Press the MENU Key ☰ to return to the main screen.
- When in Test Mode, press the RECALL Key ⮌ to display the previous test result.

RECALL KEYS AND TEST MEMORY

There are two RECALL Keys corresponding to the left and right cradles. RECALL Keys are used to view the previous test result.

To recall the previous test result, press and hold the RECALL Key. The previous test result will be displayed on a dark background to distinguish it from the current test result. Release the RECALL Key and the LCD will revert to the active screen, displaying the current test result or operation screen. Only the last test result will be held in memory, and it will remain in memory until the Reader is turned OFF. The RECALL Keys also function as UP and DOWN arrows when you are entering the code or navigating the menu.

When turned ON, the Reader LCD will display "Ready," indicating that testing may be performed. The LCD is split into left and right sides, corresponding to the left and right docking cradles.

OSMOLARITY SYSTEM ⊖ PENS

TEARLAB PENS

Each Pen contains a permanent rechargeable battery. Pens should be docked in the Reader and allowed to charge for 20 minutes before initial use. The Pen battery automatically recharges when the Pen is docked in the Reader and the power is switched ON. It is recommended that the Reader power remain ON for continuous Pen battery charging. Battery icons are located in the left and right corners of the LCD. A flashing battery icon indicates that the battery is charging. If the icon is not flashing, the battery is fully charged. Pen batteries will not overcharge.

WARNING: *Only collect tears if the green light is on. NEVER collect tears when the green light is off. If a Test Card is attached and there is no beep and no green light from the Pen, DO NOT collect tears.*

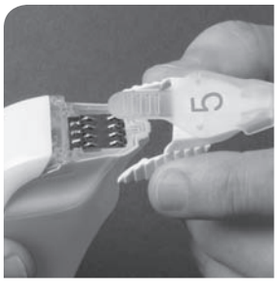
LOW BATTERY WARNING

When a Pen with low battery power is removed from the Reader, the Reader will emit two informational beeps and the "BAT LOW" message will appear on the LCD. Do not perform testing. Dock the Pen into the Reader to charge the battery. When "BAT LOW" changes to "Ready," the Pen is ready to perform a test.

LONG-TERM PEN STORAGE *Please retain Pen box and magnetic cardboard sleeve for long-term storage.*

The Pen is packaged with a magnetic cardboard sleeve that automatically turns the Pen OFF when the Pen is properly inserted. When the magnetic cardboard sleeve is removed, the Pen automatically turns ON. The Pen will remain ON indefinitely, in either Wake Mode or Sleep Mode. If the Pen is not used for 30 days or more, it is recommended to store the Pen in the magnetic cardboard sleeve and in its original box to turn the Pen OFF and to conserve the life of the battery. Failure to store the Pen properly may result in a battery that is discharged beyond its ability to recharge.

- Pen batteries are permanent and cannot be exchanged or replaced. Battery failure requires replacement of the Pen.
- The Pen battery will not overcharge.
- If the Pen has been dropped or mishandled, test with an Electronic Check Card to verify that it is functioning properly before testing patients or Control Solutions.



WAKE AND SLEEP MODES

The Pen will enter Sleep Mode when not in use and will automatically awaken when a new Test Card is attached, as indicated by the green light and the beep. The Pen will remain in Wake Mode for two minutes. If two minutes pass without tear collection, the Pen will return to Sleep Mode and the green light will turn off. To wake the Pen, remove the Test Card and reattach it onto the Pen. The green light will illuminate and the Pen will beep.

Following tear collection, a user has 40 seconds to return the Pen to the Reader before the Pen enters Sleep Mode. If the Pen enters Sleep Mode following tear collection, the data will be erased and the Test Card will not be able to be reused.

WARNING: *Pen should always be docked immediately after tear collection to avoid loss of data.*

OSMOLARITY SYSTEM ⊕ QUALITY CONTROL

CALIBRATION

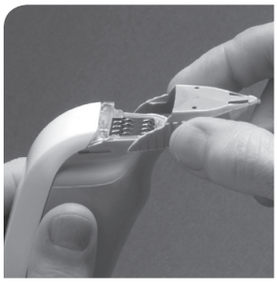
The manufacturer calibrates the TearLab Osmolarity System against a reference standard solution prepared from dried, high-purity sodium chloride traceable to the National Institute of Standards and Technology (NIST). Calibration by the user is not required.

ELECTRONIC CHECK CARD

The blue Electronic Check Card should be tested on each Pen before each day of patient testing, or if the Pen has been dropped or mishandled, to verify that the system is performing within manufactured calibration specifications. Values obtained with the Electronic Check Card should not deviate by more than +/- 3.0 mOsms/L (units of osmolarity) from the expected value.

The TearLab Osmolarity System comes with two identical blue reusable Electronic Check Cards. The Electronic Check Cards can be used simultaneously, one on each Pen, for quality control testing.

WARNING: *Fluid samples cannot be collected with the Electronic Check Card. DO NOT try to collect tears or Control Solutions with the blue Electronic Check Card.*



TESTING THE ELECTRONIC CHECK CARD

1. Attach an Electronic Check Card onto a Pen. The green light on top of the Pen will illuminate and the Pen will beep. Wait approximately five seconds for the Pen to beep again or for the green light to turn off.

2. After the green light turns off, dock the Pen into the Reader. The LCD will display a code number. It is not necessary to enter a specific code for Electronic Check Cards. Press OK to accept any code.

3. The LCD will display a test result that should fall within the expected value range indicated in the Instructions for Use provided with the Electronic Check Cards.

- Remove the Pen and press the RECALL Key to confirm that the test result was properly stored in memory.
- Repeat the procedure with the other Pen.
- Record the date and the Electronic Check Card test results in a quality log.

CONTROL SOLUTIONS

Good laboratory practice suggests the use of Normal and High Osmolarity Control Solutions to ensure that the TearLab Osmolarity System is functioning properly. Test both levels of control solution with each new shipment of test cards (even if the lot number is the same), with each new lot number, and monthly to check storage. To ensure proper performance with the TearLab Osmolarity System, only TearLab Osmolarity Control Solutions should be used. Osmolarity Control Solutions are not included with the TearLab Osmolarity System or the TearLab Osmolarity Test Cards. If correct electronic or control solution test results are not obtained, do not test patient samples; instead, contact your local sales representative or TearLab Customer Support in your area.

Please refer to the "Testing Osmolarity Controls" section on page 7 of this manual for the Osmolarity "Control Solutions" testing procedure.

CONTRAINDICATIONS

Human tear fluid samples may be used. Collect tear fluid samples directly from the eye.

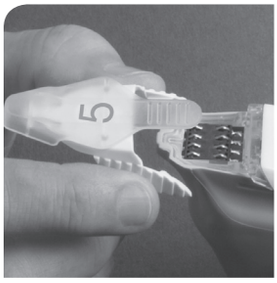
- Do not collect tear fluid from a patient within two hours of medicinal eye drop use or use of topical medications.
- Do not collect or store tear fluid samples for transport or testing at a later time.
- Do not collect tear fluid after ocular surface staining.
- Do not collect tear fluid within 15 minutes of use of anesthetic or mydriatic (dilating) eye drops or after other invasive ocular diagnostic testing.
- Do not collect tear fluid within 15 minutes after a slit lamp examination.
- Do not collect tear fluid within 15 minutes from a patient who has been crying.

WARNING: *If either the Electronic Check Card or the Control Solution test results do not match the expected value range, DO NOT test patients. Contact your local sales representative or TearLab Customer Support for assistance.*

OSMOLARITY SYSTEM → OSMOLARITY TEST

HOW TO PERFORM AN OSMOLARITY TEST

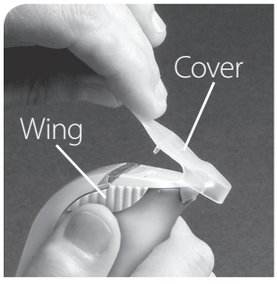
NOTE: *Use appropriate clinically hygienic methods when collecting tears.*



BEFORE EACH TEST:

- Remove either Pen from the Reader. The LCD will display "Ready."

NOTE: *DO NOT collect tear samples if the Reader does not display "Ready."*



- Remove a Test Card from its package and attach it onto the Pen. The Pen will beep and the green light will illuminate when the Card is attached properly. The green light will remain on until tears are collected or the Pen times out (after two minutes).
- Remove the protective cover by holding the wings of the Test Card firmly and pulling the sheath up and off of the Test Card.

WARNING: *A Test Card without a protective cover should be considered used. DO NOT use for patient testing.*

TEAR COLLECTION PROCEDURE

NOTE: *For Osmolarity Controls, refer to the "Testing Osmolarity Controls" section on page 7.*

- Seat the patient with chin tilted upward and eyes directed toward the ceiling.
- Place one hand on the face for stabilization. Do not pull the eyelid down or away from the eye.
- Position the tip of the Pen just above the lower eyelid.
- Gently lower the Pen until the bottom of the tip touches the thin line of moisture between the eyelid and the eye. It is not necessary to press inward toward the eye.
- The Pen will beep and the green light will turn off after a successful tear collection.

NOTE: *Sometimes when there is very little tear, the act of withdrawing the Pen breaks the surface tension of the tear meniscus and allows tears to enter the microfluidic channel. In this case, the Pen will beep upon withdrawal, indicating a successful tear collection.*

NOTE: *Tear collection should be performed at the lateral (temporal) extent of the eyelid where the risk of inadvertent injury to the cornea can be minimized, rather than adjacent to the cornea where injury is more likely.*

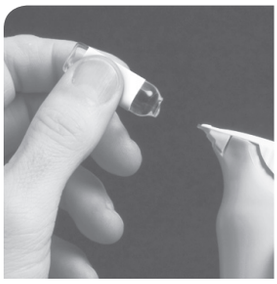
TO GET THE RESULT

- Locate the code on top of the Test Card (see example in picture).
- Dock the Pen into the Reader within 40 seconds of collecting the sample.
- Immediately press the RECALL Key ⮌ below the UP and DOWN arrows to select the Test Card code.

IMPORTANT: *If a code is not selected within eight seconds, the Reader will automatically use the default code displayed on the LCD. It is important to select the correct code to obtain an accurate osmolarity test result.*

- Press the OK Key OK or wait eight seconds to accept the code.
- The test result will display in a few seconds.
- Record the date and test result in the patient chart.

NOTE: After recording test result, remove the used Test Card from the Pen by pressing forward on top of the Test Card with your thumb. Do not pull from the wings. Dispose in an appropriate manner (reference page 10 HAZARDS).



TESTING OSMOLARITY CONTROLS

Test both levels of control solution with each new shipment of test cards even if the lot number is the same), with each new lot number, and monthly to check storage. Read the control solution instruction sheet for expected values.

- Attach a Test Card to the Pen (refer to the "How to Perform an Osmolarity Test" section on page 5 of this manual).
- Do NOT collect tears.
- Instead of collecting tears, use a control solution.
- Use the blue sleeve to snap off the top of an ampule.
- Turn the ampule upside down (the fluid will not spill out).
- Touch the tip of the Pen to the control solution.
- Return the Pen to the Reader, enter the code.
- Check control result to the expected value.
- If within the expected range patient testing may proceed.
- If not within the expected range you should not perform patient testing. Contact TearLab Customer Support in your area or call TearLab at **(858) 455-6006.**

RESULT INTERPRETATION

TearLab test results are displayed on the LCD in mOsms/L. No calculations are required. Osmotic concentration determinations are often expressed as either osmolarity (milliosmoles/liter i.e., mOsms/L or as centiosmoles/liter i.e., cOsms/L) or osmolality (milliosmoles/kilogram,i.e., mOsms/kg or as centiosmoles/kg, i.e., cOsms/kg). In tear fluid the difference between osmolarity and osmolality is insignificant, and it is common in the clinical literature to use the terms interchangeably.[5]

TearLab measurement range is linear from 275–400 mOsms/L. Test results outside this range will be reported as either "Below Range," indicating a measurement below 275 mOsms/L, or "Above Range," indicating a measurement above 400 mOsms/L. Osmolarities outside the stated range are very rare and should generally be confirmed with a subsequent test, as values outside the measurement range may be indicative of an error (e.g., user error during the test).

EXPECTED RESULTS

Reference tear osmolarity values for Normal and Dry Eye osmolarity levels.

NOTE: *Osmolarity may differ from left eye to right eye, and each eye should be tested and assessed to determine which eye represents higher osmolarity.*

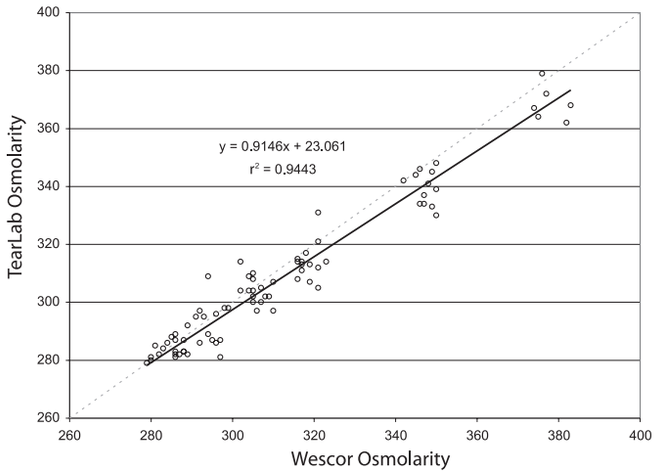
Normal: Mean 309.9 mOsms/L ± 11.0 (288–331 mOsms/L; 90% CI 288–331)
Dry Eye Disease: Mean 324.3 mOsms/L ± 20.1 (291–382 mOsms/L; 90% CI 284–392)

The results of the TearLab Osmometer should be evaluated with all clinical and laboratory data available. If the results do not agree with the clinical evaluation, additional tests should be performed. Osmolarities above or below the measurement range are very rare and should generally be confirmed with subsequent testing, as values outside the measurement range may indicate an error (e.g., user error during the test). Test only on human tears or TearLab Osmolarity Control Solutions.

ACCURACY (METHOD COMPARISON)

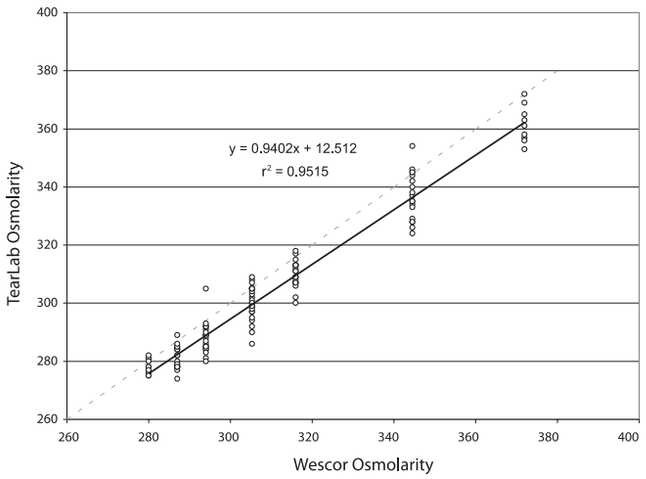
The correlation study was performed internally by the manufacturer using contrived tear samples of various osmolarity levels within the clinical reference range on both the TearLab Osmolarity System and the Wescor Model 5520 vapor pressure osmometer calibrated to NIST- traceable standards.

No. Sites	N	Regression Line	r^2
1	80	y = 0.9146x + 23.061	0.9443



At each of three physician office sites, 40 contrived tear specimens across seven levels of the clinically significant range were prepared and measured on the TearLab Osmolarity System. The physician office laboratories did not have access to the Wescor 5520 Vapro® vapor pressure osmometer. Wescor values were determined by an average of two to three measurements on each level of osmolarity immediately prior to the beginning of the study.

No. Sites	N	Regression Line	r^2
3	120	y = 0.9402x + 12.512	0.9515



CALIBRATION DATA

To determine clinical performance for tear film hyperosmolarity in the diagnosis of Dry Eye Disease, a meta-analysis was performed on historical published data for tear osmolarity in samples of Normal and Dry Eye subjects. An osmolarity referent value of 316 mOsms/L was found to yield sensitivity of 69%, specificity of 92%, and an overall predictive accuracy of 82% for the diagnosis of Dry Eye Disease. Studies in the meta-analysis used earlier osmolarity devices, not TearLab.

Performance of Osmolarity in Meta-analysis				
	Normal	Dry Eye	Total	
≤316	750	192	942	80% NPV
>316	65	429	494	87% PPV
Total	815	621	1,436	
	Specificity 92%	Sensitivity 69%		

[Tomlinson A, Khanal S, Ramaesh K, Diaper C, McFadyen A. Tear Film Osmolarity: Determination of a Referent for Dry Eye Diagnosis, Investigative Ophthalmology & Visual Science*, October 2006; 47(10) 4309-4315]*

PERFORMANCE ON PATIENTS WITH OBJECTIVE SIGNS OF DRY EYE

140 subjects were enrolled in a multicenter study (n = 45 Normal, n = 95 Dry Eye). To qualify as a Dry Eye patient, subjects were required to have a positive score on the Ocular Surface Disease Index (OSDI) and 2 or more positive indications of Tear Film Breakup Time (TBUT), Schirmer Test, Corneal Staining, Conjunctival Staining, or Meibomian Gland Dysfunction. Performance of the TearLab™ Osmolarity System using these selection criteria is shown in the table below.

TearLab Osmolarity Diagnostic Performance for Dry Eye Disease				
	Normal	Dry Eye	Total	
≤316	32	34	66	48% NPV
>316	13	61	74	82% PPV
Total	45	95	140	
	Specificity 71%	Sensitivity 64%		

Figures 1 & 2. Distribution of Osmolarities in Normal and Dry Eye Disease subjects

Figure 1

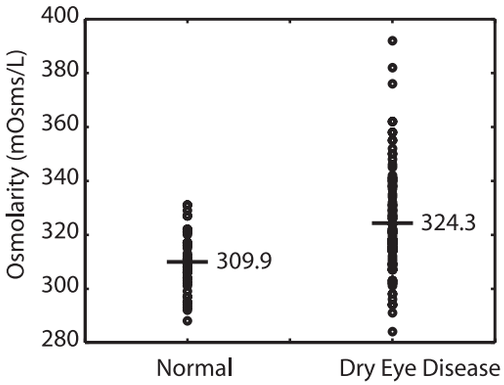
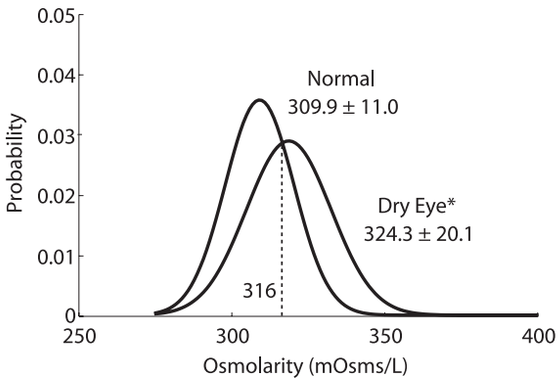


Figure 2



*Dry Eye distribution is not normal. It is skewed toward 400 mOsms/L.

OSMOLARITY SYSTEM SPECIFICATIONS

POWER REQUIREMENTS

Use only Power Supply Model PDM30US12 (XP Power)

POWER SUPPLY

Input voltage: 100–240 VAC
Input current: 0.6A MAX
Frequency: 47–63 Hz
Output voltage: 12 VDC
Output current: 2.5A
Class II
Continuous service

SYSTEM CLASSIFICATION

Class II: powered by Class II power supply
Type B applied part
Continuous service

PEN POWER SOURCE

Input: 4.5–5.5 VDC 0.6A
Internally powered by rechargeable battery
Continuous service

ENVIRONMENTAL CONDITIONS

Transport and storage temperature: 2°–35°C/36°–95°F
Transport and storage relative humidity: 10%–85% noncondensing
Transport and storage altitude: 0–2,000 meters
Operating temperature: 15°–30°C/59–86°F
Operating altitude: 0–2,000 meters
Operating relative humidity: 10%–85% noncondensing

OSMOLARITY SYSTEM HAZARDS

The TearLab Osmolarity System is designed for stability, reliability, and safety, and it has been developed, manufactured, and marketed under a quality management system certified to ISO 13485 (2003).

The TearLab Osmolarity System complies with the following materials:

- WEEE Directive 2002/96/EC Waste Electrical and Electronic Equipment
- RoHS Directive 2002/95/EC Restriction of Hazardous Substances
- IEC 60601-1 Medical Electrical Equipment — General Requirements for Basic Safety and Essential Performance

The TearLab Osmolarity Test Cards do not contain reagents or chemicals.

Equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

The American Academy of Ophthalmology (AAO) states: "Human tears are not considered to contain significant amounts of bloodborne pathogens, and thus do not require OSHA's [Occupational Safety and Health Administration's] bloodborne pathogens precautions; but exposure to human tears does require good office hygiene practices such as hand washing. However, contact with tears contaminated with blood, such as in minor surgery, requires the use of bloodborne pathogen precautions."[6]

Proper handling and disposal methods of used Test Cards should be established according to relevant state and federal regulations.

TearLab is designed to collect samples of tear fluid from the eye, a nonsterile environment. The AAO has issued guidance to minimize the transmission of ocular surface infectious agents. Prevention of transmission of these pathogens requires good hygienic techniques, such as washing hands and instruments that touch the eye. Refer to the "Maintenance" section on page 11 of this manual for information about proper cleaning of the TearLab Reader and Pen. TearLab Osmolarity Test Cards are for single use, are clinically hygienic and individually packaged, and contain a protective cover. Never reuse or attempt to clean a Test Card. Do not touch the Test Card tip after removal of the protective cover.

Although the device is manufactured to a level of disinfection deemed appropriate by the CDC (Division of Healthcare Quality Promotion; "Disinfection and Sterilization of Patient-Care Equipment, 1985"; last modified June 22, 2005), it is not sterile and there is a minimal risk of infection, ocular abrasion, or vision loss, as there is with any foreign object that is brought in direct contact with the eye, and appropriate hygiene and care should be adhered to.

FDA MEDWATCH

Report a serious adverse event, product quality problem, product use error, or therapeutic inequivalence/failure that you suspect is associated with the use of the TearLab Osmolarity System to TearLab Customer Support (Tel: 858-455-6006) and/or to FDA MedWatch (Tel: 800-FDA-1088), (Fax: 800-FDA-0178), or (www.fda.gov/medwatch).

OPERATIONAL PRECAUTIONS

- For professional *in vitro* diagnostic use only. CLIA Waived.
- Use only at ambient temperature of 15°–30°C/59°–86°F.
- Pen timer: In order to conserve battery life, the Pen is programmed to enter Sleep Mode automatically two minutes after it powers up.
- When a Pen is not being used for 30 days or more, store it in the magnetic cardboard sleeve to conserve battery life.
- Osmolarity Test Cards are stable until the expiration date marked on the label.
- Leave Test Card in its sealed pouch until use.
- Do not remove the protective Test Card cover until the Test Card is attached onto a Pen. Remove the protective cover immediately prior to tear collection.
- Any Test Card that does not contain a protective cover should not be used for patient testing. A Test Card that has been contaminated or dropped without a protective cover should not be used for patient testing.
- A measurement should not be performed if a Pen that contains a Test Card with a patient sample has been dropped. Discard Test Card and perform test with an Electronic Check Card to verify that the Pen is performing correctly.
- Avoid touching the tip of the Test Card.
- Test Cards are for single use only. Never reuse or try to clean a Test Card.
- Dock the Pen into the Reader within 40 seconds of collecting a sample or the Pen will time out (T/O). The Pen will emit a series of reminder beeps approximately 30 seconds after tear collection to prompt immediate docking. A Pen docked into the Reader after 40 seconds will display a "Pen T/O" error message; all data will be lost, and the test will be invalid.
- Test Card should not be removed after tear collection or prior to docking, or data will be lost.
- Tear collection should not be attempted if the green light on the Pen is not illuminated. The green light will not illuminate if battery power is low or the Test Card is used.
- Do not remove a Test Card from the Pen after tear collection until a measurement has been displayed. Removing a Test Card from the Pen prior to docking will clear the Pen's memory and data will be lost. The Pen will not recognize a fluid-filled Test Card if it is removed and reattached onto the Pen.
- Refer to the "Contraindications" and the "How to Perform an Osmolarity Test" sections on page 5 of this manual for tear fluid sample collection guidelines.
- Prior to use, inspect the Reader, Pen, and Test Card for physical damage. If anything is damaged, do not perform testing until the System's performance has been verified with both the Electronic Check Cards and the Osmolarity Control Solutions.

The TearLab Osmolarity System is designed to work without direct service or preventive maintenance. If quality checks fail, contact TearLab Customer Support.

The TearLab Reader and Pens can be cleaned with a damp cloth or alcohol wipe as required. When cleaning, it is important to keep the electronic contacts of the Pen and Reader dry. The electronic contacts and docking port should also be kept free of dust and dirt. Pen batteries cannot be replaced. If the Pen battery fails to recharge, contact your sales representative or TearLab Customer Support to purchase a replacement Pen. Cleaning fluids should never be used on the Test Cards.

TECHNICAL SERVICE

For technical service contact your sales representative or TearLab Customer Support. See back cover for contact information.

REPLACEMENT PARTS

To order replacement parts, contact your local sales representative or TearLab Customer Support in your area for assistance.

PROBLEM	EXPLANATION	ACTION
Test Card is attached, green light does not illuminate, and Pen does not beep.	A. Test Card is not properly attached. B. Test Card is used. C. Pen battery is low. D. Pen electrical contacts are worn.	1. Remove Test Card and reattach if protective cover is still on. NEVER use a Test Card that does not have a protective cover. 2. Dock Pen into Reader to assess battery charge level. 3. Use the Electronic Check Card to confirm Pen function. 4. Try a new Test Card. 5. Contact TearLab Customer Support.
Pen begins beeping approximately 30 seconds after tear collection.	Pen will time out in 10 seconds.	Immediately dock the Pen into the Reader. Pen must always be docked within 40 seconds of tear collection.
Pen's green light turns off with an unused Test Card attached prior to tear collection.	A. Two minutes have passed since attachment of Test Card, and Pen has entered Sleep Mode. B. Pen battery is too low for tear collection.	1. Remove unused Test Card and reattach onto Pen. Proceed with tear collection. 2. Dock the Pen to allow battery to recharge. Reader LCD will indicate battery charging status.
Electronic Check Card does not fall within the expected value range.	The TearLab Osmolarity System does not meet manufacturer specifications.	Retest using the second Electronic Check Card. If result does not fall within the expected value range, contact TearLab Customer Support.
Osmolarity Control Solution results do not fall within the expected value range.	Either Test Card or TearLab Osmolarity System does not meet manufacturer specifications.	1. Check the expiration dates of the Test Card and Osmolarity Control Solutions. 2. Test with the Electronic Check Card. A. If results are out of range, contact TearLab Customer Support. B. If results are in range, retest Osmolarity Controls. If results are still out of range, contact TearLab Customer Support. 3. Do not perform patient testing until Osmolarity Control results fall within the expected value range.
When Pen is removed from Reader, Pen beeps twice and LCD displays "BAT LOW."	Pen battery is low and testing cannot proceed.	Dock Pen into Reader to recharge battery.
Reader LCD displays "Used T/C."	Test Card has already been used. Test Cards are for single use. Pen will not accept a Test Card that has been used previously to collect tear fluid samples.	Remove the Test Card. Attach a new Test Card and proceed with testing. If necessary, the last test can be recalled by pressing and holding the RECALL Key.
Reader LCD displays "Pen T/O."	Pen was not docked into Reader within 40 seconds of tear collection. Data is lost.	Retest patient with a new Test Card. Dock Pen into Reader within 40 seconds of tear collection.
Reader LCD displays "Above Range."	Test result was above 400 mOsms/L.	Verify function with quality control procedures. Retest patient, as values outside the measurement range may be indicative of an error. Once value is confirmed, record patient result as "Above 400 mOsms/L."

PROBLEM	EXPLANATION	ACTION
Reader LCD displays "Below Range."	Test result was below 275 mOsms/L.	Verify function with quality control procedures. Retest patient, as values outside the measurement range may be indicative of an error. Once value is confirmed, record patient result as "Below 275 mOsms/L."
Need to confirm which Test Card code was entered onto Reader after an osmolarity test was performed.	Not sure if correct Test Card code was entered onto Reader during test. Osmolarity test result may be inaccurate.	Using either Pen, test with an Electronic Check Card in the same docking port as the test in question. The Test Card code that is displayed on the Reader LCD will be the same code as that of the last test performed. Verify that this Test Card code matches the code for the test in question. If it does not match, disregard the osmolarity test result.
Reader fails to detect a docked Pen.	Pen or Reader electrical contact failure.	Dock Pen, charge batteries, and retest with Electronic Check Card. If error repeats or result does not fall within the expected value range, contact TearLab Customer Support.
Reader LCD displays "E51."	Pen/Reader communication error.	Dock Pen, charge batteries, and retest with Electronic Check Card. If error repeats or result does not fall within the expected value range, contact TearLab Customer Support.
Reader LCD displays "E52."	Pen not responding to Reader.	Dock Pen, charge batteries, and retest with Electronic Check Card. If error repeats or result does not fall within the expected value range, contact TearLab Customer Support.
Reader LCD displays "E53."	Communication protocol failure between Pen and Reader.	Dock Pen, charge batteries, and retest with Electronic Check Card. If error repeats or result does not fall within the expected value range, contact TearLab Customer Support.
Reader LCD displays "E54."	Reader and Pen software do not match; size error.	Test with Electronic Check Card. If error repeats or result does not fall within the expected value range, contact TearLab Customer Support.
Reader LCD displays "E55."	Reader and Pen firmware incompatible; version error.	Test with Electronic Check Card. If error repeats or result does not fall within the expected value range, contact TearLab Customer Support.
Reader LCD displays "E56."	Pen failed premeasurement relay check.	Test with Electronic Check Card. If error repeats or result does not fall within the expected value range, contact TearLab Customer Support.
Reader LCD displays "E57."	Pen battery will not hold a charge.	Test with Electronic Check Card. If error repeats or result does not fall within the expected value range, contact TearLab Customer Support.
Reader LCD displays "E58."	Measurement attempted with uncalibrated Pen.	Test with Electronic Check Card. If error repeats or result does not fall within the expected value range, contact TearLab Customer Support.

OSMOLARITY SYSTEM ⊕ WARRANTY

The TearLab Reader and Pens ("Product") are warranted against defects in material and workmanship for 12 months from the date of delivery. The foregoing warranty is subject to the following conditions and exceptions:

Warranty excludes repair of failures resulting from mishandling or abuse. Warranty excludes consumable items such as Test Cards. Warranty does not apply to damage sustained in transit. Warranty service may be performed only by TearLab Corporation ("TearLab") or its authorized representative. Warranty is void if the Product has been modified or repaired by anyone other than TearLab or its authorized representative. Warranty is nontransferable. Warranty is void if the serial number tag is removed or altered. If the Product fails to conform to the foregoing warranty, you may return the nonconforming Product during the 12-month warranty period accompanied by (a) a copy of the sales receipt of the Product (for the purposes of evidencing the applicable warranty period) and (b) a Return Material Authorization ("RMA") number for the defective Product, obtained from TearLab prior to initiating the shipment of the defective Product to TearLab. Products returned without a sales receipt and valid RMA number shall be returned to you, with no further obligation by TearLab regarding the Product. If you return a Product in compliance with the foregoing requirements, TearLab shall repair or replace the Product as soon as is practicable.

THE REPLACEMENT OF THE NONCONFORMING PRODUCTS BY TEARLAB AS PROVIDED ABOVE SHALL BE YOUR SOLE AND EXCLUSIVE REMEDY FOR BREACH OF THE FOREGOING WARRANTY.

OTHER THAN AS WARRANTED ABOVE, THE PRODUCT IS PROVIDED AS IS. TEARLAB MAKES NO OTHER WARRANTIES RELATING TO THE PRODUCT, EXPRESS OR IMPLIED, AND EXPRESSLY DISCLAIMS ANY IMPLIED WARRANTIES, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF NONINFRINGEMENT, FITNESS FOR A PARTICULAR PURPOSE, OR MERCHANTABILITY.

In the event that you experience any difficulty with the TearLab Osmolarity System, contact your local sales representative or TearLab Customer Support.

OSMOLARITY SYSTEM ⊕ EMC AND SAFETY

SPECIFICATION	FREQUENCY RANGE
EN 55011: 2007, Group 1, Class "A" Conducted Emissions	0.15 MHz – 30.00 MHz
EN 55014-1: 2006 Disturbance (Click)	0.15 MHz – 30.00 MHz[1]
EN 55011: 2007, Group 1, Class "A" Radiated Emissions	30.00 MHz – 1000 MHz
EN 61000-3-2: 2000/A2: 2005 Power Line Harmonics	Up to the 40th Harmonic
EN 61000-3-3: 1995/A1: 2001/A2: 2005 Power Line Flicker	Less than or equal to 4% Maximum Relative Voltage Charge; Value of D (T) less than or equal to 3% for more than 200 ms

NOTE 1: No discontinuous disturbance (clicks) identified at this frequency range.

SPECIFICATION	MINIMUM TEST LEVEL REQUIRED PER EN 60601-1-2 FOR NON-LIFE-SUPPORT EQUIPMENT	TEST LEVEL COMPLETED
IEC 61000-4-2: 1995/A1: 1998/A2: 2000 - Electrostatic Discharge Immunity	Air Discharge up to ± 8kV Contact Discharge up to ± 6 kV	Air Discharge up to ± 8kV Contact Discharge up to ± 6 kV
IEC 61000-4-3: 2006 - RF Radiated Fields Immunity	Radiation Field Strength of 3V/m 80–6000 MHz (80% AM @ 1 kHz)	Radiation Field Strength of 3V/m 80–6000 MHz (80% AM @ 1 kHz)
IEC 61000-4-4: 2004 + Corrigendum 1: 2006 - Electrical Fast Transient Immunity	Power line pulses of ± 2 kV direct; I/O line pulses of ± 1 kV	Power line pulses of ± 2 kV direct; I/O line pulses of ± 1 kV
IEC 61000-4-5: 2005 - Lightning Surge Immunity	Power line surge of ± 2 kV common, ± 1 kV differential mode	Power line surge of ± 2 kV common, ± 1 kV differential mode
IEC 61000-4-6: 2004/A2: 2006 - RF Common Mode Immunity	150 kHz–80 MHz at 3 V_{RMS} 1 kHz 80% amplitude modulated	150 kHz–80 MHz at 3 V_{RMS} 1 kHz 80% amplitude modulated
IEC 61000-4-8: 1993/A1: 2000 Power Frequency Magnetic Field Immunity	Helmholtz coil at 50 Hz and 60 Hz, to 3 Amps (RMS) per meter	Helmholtz coil at 50 Hz and 60 Hz, to 3 Amps (RMS) per meter
IEC 61000-4-11: 2004 - Voltage Dips and Short Interruptions	Voltage dips of >95%, 30%, and 60%; interruptions of >95%	Voltage dips of >95%, 30%, and 60%; interruptions of >95%

The TearLab Osmolarity System is intended for use in an electromagnetic environment with controlled HF disturbances. The user of the TearLab Osmolarity System can help to avoid electromagnetic disturbances by keeping the minimum distance between portable and mobile telecommunication devices (transmitters) and the TearLab device — depending on the output power of the telecommunication devices, as described below.

	SAFETY DISTANCE DEPENDING ON THE FREQUENCY IN m		
Rated maximum output power of transmitter W	150 kHz to 80 MHz d={ 3,5/V1 }√P	80 MHz to 800 MHz d={ 3,5/E1 }√P	800 MHz to 2.5 GHz d={ 7/E1 }√P
0.01	0.12	0.04	0.08
0.1	0.37	0.11	0.22
1	1.17	0.35	0.70
10	3.7	1.11	2.22
100	11.67	3.50	7.00

For transmitters with a maximum nominal power not mentioned above: To detect the recommended safety distance, use the equation in the corresponding column. P is the maximum nominal power of the transmitter in watts (W) according to the specifications of the transmitter manufacturer.

NOTE: These guidelines may not be applicable for all cases. The propagation of electromagnetic values is influenced by absorptions and reflections of buildings, objects, and people.

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GLOSSARY OF SYMBOLS			
	Date of manufacture		Use by date
	Manufacturer	SN	Serial number
IVD	*In vitro* diagnostic device	REF	Catalog number
	Consult Instructions for Use	EC REP	Authorized representative for the European Union
CONTROL	Control		Type B applied part IEC 60601-1

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CE

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One or more of the following patents may apply: U.S. Patents 7,017,394; 7,051,569; 7,111,502; 7,129,717; 7,204,122; 8,020,433; 7,987,702; 7,905,134; 7,810,380; 7,574,902

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